EXHIBIT 40

EXHIBIT 5 2/22/06 Poulsen

TESTIMONY
Outpatient Drugs
January 6, 1998

I am Dorothy Poulsen, pharmacy program officer for the Medicaid Services Bureau of the Department of Public Health and Human Services. I will briefly describe the proposed rules and explain the Department's reasons for proposing the adoption of Rule I and amendments to ARM 46.12.102, 46.12.702 and 46.12.703 pertaining to Medicaid coverage and reimbursement for outpatient drugs.

The primary purpose of the proposed changes to the outpatient drug rules is to implement the 1.5% provider increase passed in the 1997 Montana General Appropriations Act. We have also taken this opportunity to revise portions of the rules that are no longer applicable, have caused confusion, or have outdated legal references, dates, etc.

RULE I: We have transferred definitions from ARM 46.12.102(19), (2), and (21) to Rule I because these definitions are currently in sub-chapter 1 which pertains to general requirements of the Medicaid program. Since these definitions apply specifically to outpatient drugs, they are more appropriately located within sub-chapter 7, Outpatient Drugs. A definition for "legend drugs" was added because of other revisions made in these rules. The definition of maximum allowable cost was changed because the current language is incorrect, and, if used, would overprice MAC drugs.

ARM 46.12.702 Outpatient Drugs, Requirements: The language in ARM 46.12.702(3) was changed to eliminate potential confusion about the phrase "drugs which require a prescription." Since Medicaid always requires a prescription for reimbursement, the intent of the phrase was unclear to some readers. Since this phrase was intended to refer to legend drugs, we have replaced the phrase with "legend drugs."

Revisions to ARM 46.12.702(5) eliminate references to acute and chronic conditions. These terms are ambiguous and have resulted in disputes with pharmacy providers. The intent of this rule is to specify the dispensing limits for the program when the prescriber does not order a specific quantity. The upper limits are easily defined but the minimum limits are more difficult to designate. The department's intention is that drugs be dispensed in as great a quantity, up to the limits, as is reasonable for the situation. For example, many nursing home patients use the same drugs for months or years. To dispense such drugs in less than monthly quantities is an abuse of the reimbursement methodology because frequently the major expense to the program in these cases is the dispensing fee rather than the drug product. To specify a minimum, however, would likely result in waste. To solve this dilemma, the department has left the current language "in sufficient quantities to cover the period of time for which the condition is being treated" as its minimum limit. Other changes in this rule "clean up" legal references, addresses, etc.

ARM 46.12.703 Outpatient Drugs, Reimbursement: Part (2) of the current rule contained several provisions that have been subdivided into proposed rules (2)(a), (b), (c), and (d). In (2)(a) the description of the basis for the dispensing fee has been simplified and updated and because it is obsolete, the description of the incentive factor was deleted. Part (2)(b) changes the cap for the dispensing fee to $4.14 to reflect the provider increase passed by the legislature. The other major revision of this rule is the addition of (5) describing the reimbursement for outpatient drugs provided to medicaid recipients in state institutions under the state contract.

BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

In the matter of the adoption of rule I and the amendment of 46.12.102, 46.12.702 and 46.12.703 pertaining to medicaid outpatient drugs	)))))	NOTICE OF PUBLIC HEARING OF PROPOSED ADOPTION AND AMENDMENT

TO: All Interested Persons

1. On January 6, 1998, at 9:30 a.m., a public hearing will be held in the auditorium of the Department of Public Health and Human Services Building, 111 N. Sanders, Helena, Montana to consider the proposed adoption of rule I and the amendment of 46.12.102, 46.12.702 and 46.12.703 pertaining to medicaid outpatient drugs.

The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you request an accommodation, contact the department no later than 5:00 p.m. on December 29, 1997, to advise us of the nature of the accommodation that you need. Please contact Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210; telephone (406)444-5622; FAX (406)444-1970.

2. The rule as proposed to be adopted provides as follows:

RULE I OUTPATIENT DRUGS, DEFINITIONS (1) "Outpatient drugs" means drugs which are obtained outside of a hospital.

(2) "Legend drugs" means drugs that federal law prohibits dispensing without a prescription.

(3) "Maximum allowable cost (MAC)" means the upper limit the department will pay for multi-source drugs. In order to establish base prices for calculating the maximum allowable cost, the department hereby adopts and incorporates by reference the methodology for limits of payment set forth in 42 CFR 447.331 and 447.332 (1996). The maximum allowable cost for multi-source drugs will not exceed the total of the dispensing fee established by the department and an amount that is equal to the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules or, in the case of liquids, the commonly listed size. If the drug is not commonly available in quantities of 100, the package size commonly listed will be the accepted quantity. A copy of the above-cited regulations may be

obtained from the Department of Public Health and Human Services, Health Policy and Services Division, 1400 Broadway, P.O. Box 202951, Helena, Montana, 59620-2951.

(4) "Estimated acquisition cost (EAC)" means the cost of drugs for which no MAC price has been determined. The EAC is the department's best estimate of what price providers are generally paying in the state for a drug in the package size providers buy most frequently. The EAC for a drug is the direct price (DP) charged by manufacturers to retailers. If there is no available DP for a drug or the department determines that the DP is not available to providers in the state, the EAC is the average wholesale price (AWP) less 10%.

AUTH: Sec. 53-2-201 and 53-6-113, MCA
IMP: Sec. 53-2-201, 53-6-101, 53-6-111 and 53-6-113, MCA

3. The rules as proposed to be amended provide as follows. Material to be added is underlined. Material to be deleted is interlined.

46.12.102 MEDICAL ASSISTANCE, DEFINITIONS (1) through (18) remain the same.

~~(19) Outpatient drugs means drugs which are obtained outside of a hospital.~~

~~(20) Maximum allowable cost (MAC) is the upper limit the department will pay for multi source drugs. In order to establish base prices for calculating the maximum allowable cost, the department hereby adopts and incorporates by reference the methodology for limits of payment set forth in 42 CFR 447.331 and 447.332 (1988). The maximum allowable cost for multiple source drugs will not exceed the total of the dispensing fee established by the department and an amount that is equal to 150% of the price established under the methodology set forth in 42 CFR 447.331 and 447.332 for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules or, in the case of liquids, the commonly listed size. If the drug is not commonly available in quantities of 100, the package size commonly listed will be the accepted quantity. A copy of the above cited regulations may be obtained from the Department of Public Health and Human Services, Health Policy and Services Division, 1400 Broadway, P.O. Box 202951, Helena, Montana, 59620-2951.~~

~~(21) Estimated acquisition cost (EAC) is the cost of drugs for which no MAC price has been determined. The EAC is the department's best estimate of what price providers are generally paying in the state for a drug in the package size providers buy most frequently. The EAC for a drug is the direct price (DP) charged by manufacturers to retailers. If there is no available DP for a drug or the department determines that the DP is not available to providers in the state, effective January 1, 1988, the EAC is the average wholesale price (AWP) less 10%.~~

~~The department uses the DP and AWP as weekly reported or calculated by the American druggist blue book data center or any other industry accepted data center under contract with the department or its fiscal agent.~~

(22) through (37) remain the same in text, but are renumbered (19) through (34).

AUTH: Sec. 53-2-201 and 53-6-113, MCA
IMP: Sec. 53-2-201, 53-6-101, 53-6-106, 53-6-107, 53-6-111, 53-6-113, 53-6-131 and 53-6-141, MCA

46.12.702 OUTPATIENT DRUGS, REQUIREMENTS (1) and (2) remain the same.

(3) ~~The department will participate only in the payment of drugs which require a prescription and those over the counter drugs which are included in the department drug formulary. Over the counter drugs include, but are not limited to insulin, antacids or laxatives.~~ The department will participate only in the payment of legend drugs and those over the counter drugs which are included in the department drug formulary.

(4) remains the same.

(5) Each prescription shall be dispensed in the quantity ordered ~~by the physician~~ except that:

~~(a) Prescriptions for chronic conditions for which a physician has not ordered a specific quantity shall be dispensed in quantities of 100 dosages or a minimum of one month's supply of medication.~~

~~(b)~~(a) Prescriptions ~~for acute conditions~~ for which a ~~physician~~ specific quantity has not been ordered ~~a specific quantity~~ shall be dispensed in sufficient quantities to cover the period of time for which the condition is being treated except for injectable antibiotics, which may be dispensed in sufficient quantities to cover a three day period.

~~(c)~~(b) Notwithstanding the above, prescriptions ~~for all conditions~~ may not be dispensed in quantities greater than 100 dosages or a 34-day supply, whichever is greater.

(6) The department will not participate in the payment of prescription drugs:

(6)(a) remains the same.

(b) ~~effective April 1, 1991,~~ of a manufacturer with which the secretary of HHS has not signed a drug rebate agreement as required by ~~section 4401 of the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508~~ 42 USC 1396r-8 (1997).

(c) subject to prior authorization as determined by the medicaid drug formulary committee, established and operating in accordance with ~~the Federal Omnibus Budget Reconciliation Act of 1993~~ 42 USC 1396r-8 (1997), without the existence of a prior authorization request approved by the department or its designated representative. A copy of drugs subject to prior authorization will be provided to interested medicaid providers. A copy of this listing may be obtained by writing to the Department of ~~Social and Rehabilitation~~ Public Health and Human

Services, Medicaid Services ~~Division~~ Bureau, Health Policy and Services Division, ~~111 N. Sanders, P.O. Box 4210, Helena, MT 59604 4210~~ 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(d) The department hereby adopts and incorporates by reference 42 USC 1396r-8 (1997) as a part of these rules. A copy of 42 USC 1396r-8 (1997) can be obtained by writing to the Department of Public Health and Human Services, Medicaid Services Bureau, Health Policy and Services Division, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

AUTH: Sec. 53-6-113, MCA
IMP: Sec. 53-6-101, 53-6-113, and 53-6-141, MCA

46.12.703 OUTPATIENT DRUGS, REIMBURSEMENT (1) remains the same.

~~(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually. The dispensing fee shall include the average sum of the individual provider's direct and indirect costs which can be allocated to the filling of prescriptions, plus an additional sum as an incentive factor, which shall be 7 1/2% of the average of all Montana pharmacy prescription charges for the year the cost survey is conducted. If the individual provider's usual and customary average dispensing fee for filling prescriptions is less than the foregoing method of determining the dispensing fee, then the lesser dispensing fee shall be applied in the computation of the payment to the pharmacy provider. The cost of filling a prescription shall be determined from the Montana dispensing cost survey. A copy of the Montana dispensing cost survey form is available upon request from the department. This Montana dispensing cost survey shall outline the information used in determining the actual average cost of filling a prescription for each pharmacy. A provider's failure to submit the cost survey form properly completed will result in the assignment of the minimum dispensing fee offered. The average cost of filling a prescription will be established on the basis of a determination of all direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription. The dispensing fees assigned shall range between a minimum of $2.00 and a maximum of $4.08. Out-of-state providers will be assigned a $3.50 dispensing fee.~~

(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually.

(a) The dispensing fee is based on the pharmacy's average cost of filling a prescription. The average cost of filling a prescription will be based on the direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription, as determined from the Montana dispensing fee questionnaire. A provider's failure to submit, upon request, the dispensing fee questionnaire properly completed will result in the assignment of the minimum

dispensing fee offered. A copy of the Montana dispensing fee questionnaire is available upon request from the department.

(b) The dispensing fees assigned shall range between a minimum of $2.00 and a maximum of $4.14.

(c) Out-of-state providers will be assigned a $3.50 dispensing fee.

(d) If the individual provider's usual and customary average dispensing fee for filling prescription is less than the foregoing method of determining the dispensing fee, then the lesser dispensing fee shall be applied in the computation of the payment to the pharmacy provider.

(3) ~~Notwithstanding (2) above, effective July 1, 1990, all in-state pharmacies which became or become providers after November 30, 1986,~~ In-state pharmacy providers that are new to the Montana medicaid program will be assigned an interim $3.50 dispensing fee until a dispensing fee ~~survey~~ questionnaire, as provided ~~for~~ in (2) above, can be completed for 6 months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated in accordance with (2) for the pharmacy or the ~~$4.08~~ $4.14 dispensing fee. Failure to comply with the 6 months dispensing fee ~~survey~~ questionnaire requirement will result in assignment of a dispensing fee of $2.00 ~~being assigned~~.

(4) "Unit dose" prescriptions will be paid by a separate dispensing fee ~~assigned to that pharmacy~~ of $0.75. This "unit dose" dispensing fee will ~~be based upon the average~~ offset the additional cost of packaging supplies and materials which are directly related to filling "unit dose" prescriptions by the individual pharmacy and is in addition to~~, and are documented by each individual pharmacy, plus~~ the regular dispensing fee allowed. Only one unit dose dispensing fee will be allowed each month for ~~prescriptions for chronic conditions~~ each prescribed medication. A dispensing fee will not be paid for a unit dose prescription packaged by the drug manufacturer.

(5) Reimbursement for outpatient drugs provided to medicaid recipients in state institutions shall conform with provisions of the state contract for pharmacy services. Such reimbursement shall not exceed, in the aggregate, reimbursement under (1).

AUTH: Sec. 53-6-113, MCA
IMP: Sec. 53-6-101, 53-6-113 and 53-6-141, MCA

4. The definitions at ARM 46.12.102(19), (20), and (21) apply specifically to outpatient drugs and should therefore be located within subchapter 7, Outpatient Drugs, rather than subchapter 1 which pertains to general requirements of the Medicaid program. Moving the definitions pertaining to outpatient drugs and drug costs from subchapter 1 to subchapter 7 requires the deletion of ARM 46.12.102 (19), (20), and (21) and the adoption of RULE I OUTPATIENT DRUGS, DEFINITIONS.

The definition of maximum allowable cost (MAC) in RULE I has been changed from the version at ARM 46.12.102(20) by deleting "150% of." This deletion is necessary to accurately price MAC drugs. Since the MAC price defined in 42 CFR 447.331 and 447.332 is equal to "150% of" the calculated price, the MAC price cannot be 150% of 150% of the calculated price. To retain the current language would mean that we would overprice MAC drugs in violation of federal rule.

Adopting a definition of "legend drugs" is necessary in Rule I and because the changes in ARM 46.12.702(3) are necessary to convey clearly which drugs will be reimbursed by Medicaid. The phrase "drugs which require a prescription" in ARM 46.12.702(3) is unnecessarily confusing in that Medicaid requires recipients to have prescriptions for all drugs that are reimbursed. The distinction intended in the rule is between legend drugs (drugs that federal law prohibits dispensing without a prescription) and over-the-counter drugs (drugs that federal law allows to be dispensed without a prescription). Medicaid reimburses for very few over-the-counter drugs and those drugs are listed in the department's formulary.

The deletion of "physician" in ARM 46.12.702(5) and (5)(a) is necessary because other licensed practitioners also may prescribe medications and the limitations on dispensing quantity apply regardless of who prescribes. This change is to correct the internal inconsistency in the rule as written which in some parts may be interpreted to limit licensed practitioners who can prescribe drugs.

Limiting the dispensing quantity through reference to "chronic conditions" and "acute conditions" in ARM 46.12.702(5) has been changed because of disputes with pharmacists over the meaning of these terms. Some pharmacists contend that the distinction between chronic and acute conditions is not valid since patients can have acute episodes of chronic diseases. Some pharmacists also argue that prescribers do not indicate on prescriptions whether a drug is for a chronic or acute condition. The proposed rule changes remove the contentious language.

Some aspects of the methodology for determining the provider's dispensing fee described in ARM 46.12.703(2) are now obsolete and have been revised in the proposed rule. For example, when the rule was first written, the cost of filling a prescription was less than the dispensing fee cap and therefore a pharmacy could qualify for an incentive factor of 7.5% of the average of all Montana pharmacy prescription charges for the year. The incentive factor is no longer used because the cost of the filling a prescription is greater than the allowed dispensing fee cap. Therefore, the incentive factor has been deleted in the proposed rule. The current rule also has redundant language. For instance, using the direct and indirect costs of

filling a prescription is mentioned twice within the same rule. The revised language more clearly and succinctly describes the current methodology used in determining the dispensing fee.

The increase in the dispensing fee cap in ARM 46.12.703 to $4.14 is required to implement the 1.5% provider increase allowed for the pharmacy program in the 1997 General Appropriations Act (Chapter 551, Laws of Montana, 1997). The cap increase became effective July 1, 1997 in order to coincide with the state fiscal year.

Deletion of the phrase "prescriptions for chronic conditions" in ARM 46.12.703(4) is required to correspond with changes made to ARM 46.12.702(5). With this change, the pharmacy clearly may not charge the department the additional fee more than once per month even if the medication is dispensed more frequently. The other revisions are required because the unit dose fee is no longer assigned to pharmacies but is paid to any pharmacy which incurs the expense of preparing a unit dose prescription. The department also recognizes that the unit dose fee of $0.75 does not exceed the cost of preparing a unit dose prescription and therefore has removed the documentation requirement. Note that some medications are distributed in unit dose packages by manufacturers and pharmacies are not allowed to charge a unit dose fee for such medications.

The proposed rule change in ARM 46.12.703(5) is necessary because the Medicaid pharmacy program participates in the state's contract for pharmacy services for people in the state institutions. The reimbursement methodology under the state contract differs from the methodology described elsewhere in the rules because the state participates in a multi-state cooperative to buy medications and the state-contracted pharmacy provider is limited to billing the state's cost. Thus, the dispensing fee is the only avenue for the pharmacy provider to recover the cost of providing the service and this fee exceeds the cap set for other pharmacies. Analysis by the department prior to entering into the contract showed that the two reimbursement methodologies resulted in comparable costs to the outpatient drug program.

Other revisions in the proposed rules are necessary to update legal references, dates, and addresses that are no longer valid.

In revising the Medicaid outpatient drug rules, the Department's primary purpose is to implement the 1.5% provider increase passed in the 1997 Montana General Appropriations Act. The Department realized, however, that the current rules had developed over a period of years and included redundant language, outdated references, and provisions that were no longer applicable or caused confusion. Thus, the Department has taken this opportunity to correct these problems. The four

substantive changes in the proposed rules are the provider increase, deletion of the incentive factor in the dispensing fee calculation, deletion of references to acute and chronic conditions, and the adoption of a reimbursement methodology for state-contracted pharmacy services. In making these changes, the Department consulted the Montana Pharmaceutical Association and considered a number of options.

As an alternative, the 1.5% provider increase could have been applied to the product component rather than the dispensing fee. For example, the Department could have altered its method of calculating product cost to pay average wholesale price (AWP) less 8.5%. The decision not to apply the increase in this way was based on several factors. First, federal regulations require that the State pay the estimated acquisition cost of the drug. Studies of the AWP suggest that it overstates pharmacies' acquisition costs by 10 to 20%. Thus, in order to meet federal assurance requirements, the State cannot pay more than AWP less 10%. Second, the current methodology provides an automatic provider increase by paying pharmacies more as drug prices increase. Since the 10% discount does not vary with drug price increases, pharmacies receive a relatively larger reimbursement as prices increase. Third, applying the increase to the dispensing fee provides the most equitable compensation for services since it applies to each prescription dispensed. In this way, the Department ensures that a pharmacy dispensing a low cost generic drug receives a provider increase.

As an alternative to eliminating the incentive factor, the Department could have considered incorporating an incentive factor in the calculation of the dispensing fee in the proposed rule. Since almost all pharmacies already qualify for the dispensing fee cap, however, including an incentive factor would have required a significant increase (more than 1.5%) in the cap. Additionally, the Department realizes that because of the competitive nature of the healthcare marketplace, the proposed dispensing fee is competitive with that paid in other states and by other third-party payers, and no incentive factor is needed to enroll an adequate network of Medicaid pharmacy providers.

Rather than deleting references to acute and chronic conditions, the Department could have adopted operational definitions for these terms. For example, a chronic condition could have been defined as a condition for which the same medication has been prescribed for 90 days. Such a definition would be arbitrary and have no medical basis. It would also assume that the pharmacy knew how long the patient had been on a medication. By expecting the pharmacist to fill a prescription in sufficient quantity to cover the treatment period, the Department is relying on pharmacists' professional requirements which include conferring with prescribers and counseling patients on appropriate drug use.

As an alternative to adopting a different reimbursement methodology for state-contracted pharmacy services, the Medicaid program could have refused to participate in the state contract. Such refusal, however, would have been detrimental to the state institutions and would not have benefitted the Medicaid program. The proposed option recognizes the uniqueness of state institutional providers in comparison with individual pharmacy dispensed drugs to an individual medicaid recipient. The adoption of a different methodology for state institutions is not more costly in the aggregate to the medicaid program.

The changes as proposed will increase payments by an estimated $60,000 per year.

5. Interested persons may submit their data, views or arguments either orally or in writing at the hearing. Written data, views or arguments may also be submitted to Dawn Sliva, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena, MT 59604-4210, no later than January 12, 1998. The Department also maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. For placement on the mailing list, please write the person at the address above.

6. The Office of Legal Affairs, Department of Public Health and Human Services has been designated to preside over and conduct the hearing.

Dawn Sliva
Rule Reviewer

Director, Public Health and Human Services

Certified to the Secretary of State December 1, 1997.